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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/349,194	07/07/1999	KENNETH F. BUECHLER	244/121	6285

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EXAMINER

GABEL, GAILENE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 02/08/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/349,194

Applicant(s)

BUECHLER ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/20/01- CPA.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 85-96, 102-106 and 114-142 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 85-96, 102-106, and 114-142 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/24/01 in Paper No. 16 has been entered.

Amendment Entry

2. Applicant's amendment and response are acknowledged. Claims 85, 88, 91, 94, 102, 114, and 119 have been amended. Currently, claims 85-96, 102-106, and 114-142 are pending and under examination.

Rejection Withdrawn

3. In light of Applicant's amendment and arguments, the rejection of claims 114-115, 119-120, and 139-140 under 35 U.S.C. 102(b) as being anticipated by Bodor et al. (Clinical Chemistry, 1992), is hereby, withdrawn.

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4. In light of Applicant's amendment and arguments, the rejection of claims 85-93, 116-118, 121-123, and 134-136 under 35 U.S.C. 103(a) as being unpatentable over Bodor et al. (Clinical Chemistry, 1992), is hereby, withdrawn.

5. In light of Applicant's amendment and arguments, the rejection of claims 94-96, 102-106, and 137-138 under 35 U.S.C. 103(a) as being unpatentable over Katus et al. in view of Bodor et al. (Clinical Chemistry, 1992), is hereby, withdrawn.

Rejection Maintained

6. Claims 124-125 and 141 stand rejected under 35 U.S.C. 102(b) as being anticipated by Bodor et al. (Clinical Chemistry, 1992) for reason of record.

7. Claims 126-128 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bodor et al. (Clinical Chemistry, 1992) for reason of record.

8. Claims 129-133 and 142 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Katus et al. in view of Bodor et al. (Clinical Chemistry, 1992) for reason of record.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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9. Claims 85-96, 102-106, and 114-142 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In line 12 of claim 85, after "free and complexed cardiac specific", "isoform" should be --isoforms--.

Claim 85, in lines 13-15, is confusing in reciting, "wherein said signal is at least a factor of two larger than a signal resulting from **said antibody** binding to an equal number of (i) free troponin ... which are not said cardiac specific isoform of troponin; (ii) troponin complexes ... which do not comprise said cardiac specific isoform of troponin; or (iii) a combination ..." because the recitation of this "said antibody" lacks antecedent support. Specifically, the antibody recited in the previous steps of claim 85 appears to only be specific for cardiac specific isoforms; therefore, the antibody should not bind, or are required not to cross-react, with those that are not cardiac specific, i.e. skeletal isoforms. Alternatively, if Applicant intends that "said antibody" in lines 13-15 is the same as those recited in the previous steps of the claim and supposedly binds both cardiac specific and not cardiac specific isoforms, it becomes unclear how the detection of free and complexed cardiac specific isoform is performed as required by the preamble. Further, if "said antibody" in lines 13-15 is indeed the same as the antibody recited in the previous steps of the claim, but can differentially bind, by virtue of increased affinity or avidity towards the cardiac specific troponin isoform and decreased affinity or avidity towards the non-cardiac specific troponin isoform, then such property should be distinctly recited. Accordingly, it is also unclear what Applicant intends to

encompass in reciting, "said signal is a factor of two larger than a signal from said antibody". Applicant is reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

In line 17 of claim 85, after "free and complexed cardiac specific", "isoform" should be --isoforms--.

Same analogous comments and problems set forth in claim 85 apply to claim 88, claim 91 which recites an assay specific for cardiac specific troponin I, and claim 94 which recites an assay specific for cardiac specific troponin T.

Claim 102 is indefinite in reciting, "said signal is related to the presence or amount of" because it is unclear what is encompassed by the term "related" as recited in the claim, i.e. indicative of, etc. See also claims 114, 119, 124, and 129.

Claim 87 lacks antecedent support in reciting, "said minimum signal".

Claim 93 lacks antecedent support in reciting, "said minimum signal".

Claim 96 lacks antecedent support in reciting, "said minimum signal".

In the preamble of claim 102, after "all free and complexed cardiac specific", "isoform" should be --isoforms--.

In line 13 of claim 102, after "all free and complexed cardiac specific", "isoform" should be --isoforms--.

In the preamble of claim 114, after "free and complexed cardiac specific", "isoform" should be --isoforms--.

In line 13 of claim 114, after "free and complexed cardiac specific", "isoform" should be --isoforms--.

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In the preamble of claim 119, after "free and complexed cardiac specific", "isoform" should be --isoforms--.

Claim 119 is vague and indefinite in reciting, "an antibody that binds to free cardiac specific troponin I and cardiac specific troponin T" because it is unclear as to whether Applicant intends for the antibody to bind "free cardiac specific troponin T" in this recitation.

In lines 12-13 of claim 119, "detecting a signal ... from said antibody binding said free and complexed cardiac specific isoforms" lacks clear antecedent support because the previous method steps required said antibody binding 1) free and complexed cardiac specific troponin I and 2) free and complexed cardiac specific troponin T.

In line 14 of claim 119, after "free and complexed cardiac specific", "isoform" should be --isoforms--.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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10. Claims 85-96, 102-106, and 114-142 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-5, 8, 10-12, 14-18 of U.S. Patent No. 5,795,725. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Buechler et al. differ from the claimed invention in failing to teach the comparative levels of intensity signals taught in claims 85, 87, 88, 90, 91, and 93, setting forth the level of signal intensity produced by antibody binding with free and complexed cardiac specific isoforms, i.e. greater by at least a factor of 2 or 5 larger than minimum signal. Buechler et al. also differ from the claimed invention in failing to teach correlation values taught in claims 104-106, 116-118, 121-123, and 126-128 wherein detectable signal is equal, a factor of 0.2, and a factor of 2 for equal amounts of all, free and complexed, cardiac specific isoforms of troponin.

However, the signal intensity levels and ranges recited in the claims that correlate the binding of antibodies and cardiac isoform specificity or concentration in troponin assays, are representative of result effective variables which may be altered in assay optimization procedures. "No invention is involved in discovering optimum ranges of a process by routine experimentation." *Id.* at 458, 105 USPQ at 236-237. The "discovery of an optimum values of a result effective variables in a known process is ordinarily within the skill of the art." *Application of Boesch*, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable values of the teaching of Buechler et al. by normal optimization procedures known in troponin assays.

Response to Arguments

11. Applicant's arguments filed 9/24/01 as applied to claims 124-133 and 141-142 have been fully considered but they are not persuasive.

Applicant argues that Bodor fails to teach or suggest using antibodies that bind all of cardiac specific isoforms of troponin including free, binary, and ternary complexes in an assay. Further, Applicant argues that the combination of Katus with Bodor also fail to suggest antibodies that bind all of cardiac specific isoforms of troponin including free, binary, and ternary complexes in an assay.

In response, use of antibodies that bind all of cardiac specific isoforms of troponin including free, binary, and ternary complexes in an assay, upon which applicant relies is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday, 6:30 AM - 4:00 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 308-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gailene R. Gabel
Patent Examiner
Art Unit 1641

grg
2/4/02

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641